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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,272	08/13/2001	Christoph Kirsch	4038-001	3234
30448 7590 05/17/2007 AKERMAN SENTERFITT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188			EXAMINER MARVICH, MARIA	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 05/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/831,272

Applicant(s)

KIRSCH ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) 1,4-7,10-21,23-38,40 and 46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22 is/are allowed.
- 6) ☒ Claim(s) 2,8,39 and 47 is/are rejected.
- 7) ☒ Claim(s) 3, 9, 42-45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Declaration

The Declaration under 37 CFR 1.132 filed 3/12/07 is sufficient to overcome the rejection of claims 2, 8 and 39 based upon Van de Locht et al and Van de Locht et al in view of Pears and Williams, Searle et al and Comai et al. Specifically, the amendment to the claims to encompass a specific increase in expression level and the evidence of the declaration provides a basis that the promoter disclosed in the cited art would not meet the limitations of the claims.

A new rejection under 35 USC 112, first paragraph, has been made. To the extent the declaration applies to this rejection, it is noted that the embodiment of at least 10x provides for a range that is greater than 10 and much higher without any upper limit. The specification specifically contemplates 20x, 30x. While the evidence in the declaration provides evidence that the promoter in the art would fail to meet the limitation of the claims, it does provide further evidence that the increase in expression would be limited in the upper range. The basis of the rejection will be discussed in greater detail below.

Claim Objections

Claims 2, 3 and 42 are objected to because of the following informalities: the claims refer to the cis-acting element of SEQ ID NO:11 in each of the claims by recitation "cis acting elements consists of a nucleotide sequence of SEQ ID NO:11". However, it is clear from the

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specification that the element consists of the entire sequence and not just a dinucleotide or some variation of a dinucleotide as implied by the use of the article "a". Therefore, it would be remedial to recite -- cis-acting elements consists of the nucleotide sequence of SEQ ID NO:11--.

Similarly, claims 42 and 43 refer to at least one cis -acting element that "comprises at least one (two) nucleotide sequence of SEQ ID NO:11 and at least one (two) nucleotide sequence of SEQ ID NO:7". It is clear that the claim does not intend that a single nucleotide or dinucleotide from SEQ ID NO:11 and 7 is to be included in the cis-acting element. Rather the promoter comprises at least one copy of two copies of the element consisting of SEQ ID NO:11 and 7. Hence, it would be remedial to recite -- comprises at least one (two) copies of the nucleotide sequence of SEQ ID NO:11 and at least one (two) copies of the nucleotide sequence of SEQ ID NO:7--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 8, 39 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chimeric promoter capable of mediating local gene expression in plants upon pathogen infection wherein the promoter comprises at least one element consisting of SEQ ID NO:11 and induction is between 10 and 15 fold and a chimeric promoter capable of mediating local gene expression in plants upon pathogen infection wherein

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the promoter comprises either two elements consisting of SEQ ID NO:11 or the promoter comprises the combination of one copy of SEQ ID NO:11 followed by one copy of SEQ ID NO:7 or 4 copies of SEQ ID NO:11 followed by four copies of SEQ ID NO:7 and induction is greater than 15 fold, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

This is a new rejection necessitated by applicants' amendment.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to a chimeric promoter that is capable of directing elicitor-specific expression of a nucleic acid. The chimeric promoters are recited as inducing expression upon elicitor treatment of pathogen infection at least 10 or 15 fold. The scope of the invention is extremely broad as the promoter is only so limited by comprising two or more cis-acting elements wherein at least one of the said elements consist of SEQ ID NO:11. Hence, any number of combinations of cis-acting elements can be contemplated in the chimeric promoter. However, the activity of the promoter must be at least 10 or 15 fold upon elicitor treatment of

pathogen infection. It is highly unpredictable based upon the teachings of the instant specification that any combination will lead to these increased levels of induction.

The specification teaches the identification of 7 elements that are capable of elicitor responsive expression alone or in combination with one another. The instant claims are directed to chimeric promoters that are constructed using SEQ ID NO:11 or element D. Specifically, the claims are directed to a chimeric promoter comprising at least two or more cis-acting elements wherein at least one of the elements are SEQ ID NO:11. This encompasses two types of chimeric promoters, those with homomers of SEQ ID NO:11 or heteromers comprising SEQ ID NO:11 in combination with other elements. As to homomers of SEQ ID NO:11, the specification teaches that only a dimer of SEQ ID NO:11 reaches levels higher than 15 fold. A tetramer only induces expression 11 fold. Hence, in order for the level of induction to be greater than 15 fold, a homomeric promoter must comprise two copies of SEQ ID NO:11. The specification teaches that for heteromeric chimeric promoters, the combination of required elements, the order of elements and number of elements is highly unpredictable. Again two copies of SEQ ID NO:11 appear to provide adequate induction in combination with two copies of either SEQ ID NO:4 or 7. However, 4 copies of SEQ ID NO:11 do not except in combination with 4 copies of SEQ ID NO:7 and when SEQ ID NO:11 is placed first in the promoter. The specification teaches this is due to steric hindrance (see page 37). Further confusing the issue is the inability of SEQ ID NO:11 when placed first with SEQ ID NO:4 to provide induction levels of greater than 15 fold. Hence, the chimeric promoter must have two copies of SEQ ID NO:11 or else be in combination with SEQ ID NO:7 such that SEQ ID NO:11 is placed prior to SEQ ID NO:7 in order to reach induction levels of greater than 15 fold.

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Given the lack of guidance in the specification, the large and diverse group of chimeric promoters recited and the highly unpredictable nature of the ability to predict components to produce a promoter with induction levels of greater than 15 fold, it is concluded that a person of skill in the art would have had to conduct undue experimentation in order to practice the claimed

Conclusion

Claims 2, 8, 39 and 47 are rejected.

Claims 2, 3 and 42-45 are objected to.

Claim 22 is allowable as the art does not teach an isolated element comprising SEQ ID NO:11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Maria B Marvich, PhD
Examiner
Art Unit 1633

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